CLAIMS

1. Polysaccharide double-layer microcapsules constituted by an outer layer of chitosan and an inner layer of alginate characterized in that they are obtained:

- from solutions of alginate with initial concentrations ranging from 2 to 4% w/v;
- from solutions of chitosan with initial concentrations ranging from 0.1 to 0.5 % w/v;
- from solutions of divalent ions with concentrations of 0.5% w/v, when the divalent ion functions as a gelification agent of the alginate to form single-layer capsules of alginate encapsulating at least one biologically active substance, and ranging from 10 to 15% w/v when the divalent ion has a stabilizing function of the double layer capsules

for use as carriers for the oral administration of said biologically active substances.

2. Polysaccharide double-layer microcapsules as claimed in claim 1, wherein a further polymer, hydroxypropylmethylcellulose, at the initial concentration of 0.4% w/v, is dispersed in the initial solutions of alginate.

3. Polysaccharide double-layer microcapsules as claimed in claim 1, wherein the initial concentration of alginate is 4% w/v, the initial concentration of chitosan is 0.1% w/v and the divalent ion with stabilizing function on the double layer microcapsules has an initial concentration of 15% w/v.

4. Polysaccharide double-layer microcapsules as claimed in claim 1, wherein the divalent ion is calcium.

5. Polysaccharide double-layer microcapsules as claimed in claim 1, wherein the biologically active substances are selected from immunomodulants, antigens, chemotherapeutics, cytokines and growth factors.

6. Polysaccharide double-layer microcapsules as claimed in claim 1, wherein an adjuvant is associated with the biologically active substance to increase the biological response.

7. Polysaccharide double-layer microcapsules as claimed in claim 1 and 6, wherein the biologically active substance or adjuvant is lysozyme.

8. Polysaccharide double-layer microcapsules with double layer of polysaccharides constituted by an outer layer of chitosan and an inner layer of alginate characterized in that they are obtained through:

a) formation of single-layer capsules encapsulating at least one biologically active substance starting from solutions of alginate in concentrations ranging from 2 to 4% w/v, in which said substance is dispersed, by gelification with a solution of a divalent ion at a concentration of 0.5% w/v;

b) formation of the second layer of chitosan and stabilization of the double-layer microcapsule obtained by adding a solution of chitosan in concentrations ranging from 0.1 to 0.5% w/v and containing a divalent ion in concentrations ranging from 10 to 15% w/v in the solution containing the single-layer capsules of alginate encapsulating said substance obtained in a).

for use as carriers for the oral administration of said biologically active substances.

9. Polysaccharide double-layer microcapsules as claimed in claim 8, wherein a further polymer, hydroxypropylmethylcellulose, at the initial concentration of 0.4% w/v, is dispersed in the initial solutions of alginate.

10. Polysaccharide double-layer microcapsules as claimed in claim 8, wherein the initial concentration of alginate is 4% w/v, the initial concentration of chitosan is 0.1% w/v and the divalent ion with stabilizing function on the double layer microcapsules has an initial concentration of 15% w/v.

11. Polysaccharide double-layer microcapsules as claimed in claim 8, wherein the divalent ion is calcium.

12. Polysaccharide double-layer microcapsules as claimed in claim 8, wherein the biologically active substances are chosen from immunomodulants, antigens, chemotherapeutics, cytokines and growth factors.

13. Polysaccharide double-layer microcapsules as claimed in claim 8, wherein an adjuvant is associated with the biologically active substance to increase the biological response.

14. Polysaccharide double-layer microcapsules as claimed in claim 8 and 13, wherein the biologically active substance or adjuvant is lysozyme.

15. Use of polysaccharide double-layer microcapsules as claimed in one of the claims from 1 to 14 for the preparation of compositions for oral administration of at

least one biologically active substance for vaccinogenic or therapeutic purposes for the prophylaxis and therapy of infectious or non-infectious diseases in the human and veterinary field.

16. Use of polysaccharide double-layer microcapsules as claimed in claim 15 for the prophylaxis and therapy in the animal breeding or fish farming field.

17. Composition of polysaccharide double-layer microcapsules as claimed in one of the claims from 1 to 14, in formulations suitable for oral administration selected from solid forms, such as powders, tablets, capsules, or liquid forms, such as oily or aqueous solutions, both for multiple dosage and in single doses as excipients or diluents acceptable from the pharmaceutical and feeding viewpoint in the human and veterinary field.

18. Process for preparation of polysaccharide double-layer microcapsules constituted by an outer layer of chitosan and an inner layer of alginate characterized in that it comprises the following phases:

a) formation of single-layer capsules encapsulating at least one biologically active substance starting from solutions of alginate in concentrations ranging from 2 to 4% w/v, in which said substance is dispersed, by gelification with a solution of a divalent ion at a concentration of 0.5% w/v;

b) formation of the second layer of chitosan and stabilization of the double-layer microcapsule obtained by adding a solution of chitosan in concentrations ranging from 0.1 to 0.5% w/v and containing a divalent ion in concentrations ranging from 10 to 15% w/v in the solution containing the single-layer capsules of alginate encapsulating at least one biologically active substance obtained in a).

19. Process for preparation of polysaccharide double-layer microcapsules as claimed in claim 18, wherein added to phases a) and b) is the phase c) of dehydration, isolation and drying of the microcapsules obtained.

20. Process for preparation of polysaccharide double-layer microcapsules as claimed in claim 18, wherein a further polymer, hydroxypropylmethylcellulose, at the initial concentration of 0.4% w/v, is dispersed in the initial solutions of alginate.

21. Process for preparation of polysaccharide double-layer microcapsules as claimed in claim 18, wherein the initial concentration of alginate is 4% w/v, the

initial concentration of chitosan is 0.1% w/v and the divalent ion with stabilizing function on the double layer microcapsules has an initial concentration of 15% w/v.

22. Process for preparation of polysaccharide double-layer microcapsules as claimed in claim 18, wherein the divalent ion is calcium.

23. Process for the preparation of microcapsules as claimed in claim 18, wherein the biologically active substances are chosen from immunomodulants, antigens, chemotherapeutics, cytokines and growth factors.

24. Process for preparation of polysaccharide double-layer microcapsules as claimed in claim 18, wherein an adjuvant is associated with the biologically active substance to increase the biological response.

25. Process for preparation of polysaccharide double-layer microcapsules as claimed in claim 18, wherein the biologically active substance or adjuvant is lysozyme.